IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GALDERMA LABORATORIES L.P., GALDERMA, S.A. and NESTLE SKIN HEALTH S.A.,	)	
Plaintiffs,	)	C.A. No. 17-1783-RGA
v.	)	
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

J. Caleb Boggs Courthouse
844 North King Street
Wilmington, Delaware

Thursday, October 31, 2019
2:30 p.m.
Oral Argument

BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL LLP
BY: JACK B. BLUMENFELD, ESQUIRE

-and-

MUNCK WILSON MANDALA, LLP
BY: MICHAEL C. WILSON, ESQUIRE
BY: JAMIL N. ALIBHAI, ESQUIRE
BY: KELLY CHEN, ESQUIRE

For the Plaintiffs

APPEARANCES CONTINUED:

SHAW KELLER LLP
BY: KAREN E. KELLER, ESQUIRE

-and-

KIRKLAND & ELLIS, LLP
BY: LEORA BEN-AMI, ESQUIRE
BY: JUSTIN BOVA, ESQUIRE
BY: THOMAS F. FLEMING, ESQUIRE
BY: NOAH FRANK, ESQUIRE
BY: ASHLEY ROSS, ESQUIRE

For the Defendant

*** PROCEEDINGS ***

DEPUTY CLERK: All rise.

THE COURT: All right. Good afternoon, everyone. Please be seated. This is the time set for the motion for injunction pending appeal in Galderma versus Teva, Civil Action Number 17-1783.

Mr. Blumenfeld, who have you got with you here?

MR. BLUMENFELD: Thank you, Your Honor. Jack Blumenfeld from Morris Nichols for the plaintiffs, and with me today are Mike Wilson, Jamil Alibhai, and Kelly Chen from the Munck Wilson firm. And in the first row in the back, Steve Midgley from Galderma.

THE COURT: All right. Thank you, Mr. Blumenfeld.

Ms. Keller.

MS. KELLER: Good afternoon, Your Honor. Karen Keller from Shaw Keller on behalf of the defendants. Here

with me today is Leora Ben-Ami, Tom Fleming, Ashley Ross, Noah Frank, and Justin Bova. And in the back, we have Rivka Jungreis and Colman Ragan from Teva.

THE COURT: All right. Well, good afternoon to all of you.

So Mr. Wilson, I guess this is your motion.

MR. WILSON: Yes, Your Honor, at least partially. If I may, I am going to be handling the issues relating to the likelihood of success that address the Court's opinion, and then Mr. Alibhai is prepared to address the issues of irreparable harm. He put together the evidence and is prepared to argue those issues.

THE COURT: Okay.

MR. WILSON: Your Honor, the question being presented is whether or not Teva should be allowed to continue to sell its generic version of Soolantra which is going to indisputably destroy the market for Soolantra over the next six-months. Even though there's a substantial question on appeal relating to the Court's opinion, and even if the Court's opinion is reversed, that will never repair the damage to Galderma because of an agreement with the second filer that will allow that second filer to remain on the market if the Court does not issue an injunction.

THE COURT: So there seemed to be some -- and I appreciate that you all have done this under somewhat of a

time pressure. I wasn't real clear, and I guess I'll start off by saying, I did read the briefs, and I did reread my opinion from Docket Item 257, and I read Mr. Hausman's opening declaration and his reply declaration. I've read Mr. Gambino's opening declaration and his reply declaration.

I've read Mr. Bart's declaration. I've read Mr. Hofmann's declaration. And I read the declaration of Mr. Cassidy submitted in connection with the reply. But maybe because I read all that stuff, I wasn't necessarily clear about all of it.

In terms of the generic, besides for Teva, we have the authorized generic which I guess is Plasco or Prasco, something like that, and we have the Perrigo generic. And so the Plasco or Prasco, whatever they are, they either have been authorized, or they haven't themselves launched.

MR. WILSON: They've been authorized and have launched an authorized generic of Galderma. That's correct, Your Honor.

THE COURT: Okay. And so Perrigo's position is that they are at the present time blocked by Teva for 180 days since Teva launched; right?

MR. WILSON: They are blocked both by the statutory exclusivity as well as the agreement that they signed with Galderma. That's correct.

THE COURT: Okay. And so the launch of your authorized generic, what effect does that have on Perrigo's ability to launch in the future?

MR. WILSON: So the launch of an authorized generic like Teva's launch acts as a potential license to Perrigo. They have to wait 180 days based on the statutory exclusivity. But as what I first mentioned when I raised the question is that if the Court issues an injunction, if there's an injunction in the next 90 days, there's a reset essentially for Perrigo's ability to launch.

THE COURT: And is the reset then just back to whatever the contract provided for them, or what is that reset?

MR. WILSON: Yes, Your Honor. The reset would be to the next event that would trigger a license. For example, if Teva were to win on appeal, and then launch again, if the Court granted an injunction and removed the injunction after the appeal, they would get to launch 181 days after Teva's next launch.

THE COURT: And so the reason for the 90-day thing is essentially that's sort of a matter of practicality which is presumably for Perrigo to launch, they have to ramp up, and get supply, and do stuff. So after 90 days, I guess, maybe as part of the whatever agreement you made with them, but that that's just giving them a reasonable amount

of time to respond. That's essentially why the 90 days is there?

MR. WILSON: I think it's more the situation where there's a launch at risk. It's a standard, as far as I understand, a fairly standard agreement. But it's essentially to address the situation of when there is a launch at risk or some other unauthorized launch that Galderma has an opportunity to get a Court to intervene like through this motion, and therefore, block Perrigo's otherwise contractual right to launch.

THE COURT: Okay. All right.

And so basically I hate to appear to be too dense here, but what you're telling me is 90 days after your authorized generic is launched, if it's still out there, then Perrigo's going to be able to launch no matter what happens with Teva; right?

MR. ALIBHAI: That's right. After 180 days after Teva's launch, they would be permanently on the market which is why the irreparable harm in this particular case is different than it may be in other cases. And that is, even if the Court agrees that there's potential for reversal of the Court's opinion, and even if Galderma succeeds in reversing, that reversal will not remove the generic from the market. This is a permanent presence of a generic on the market if an injunction is not entered within 90 days of

Teva's launch at risk.

THE COURT: Okay. Well, thank you. That's helpful.

So you want to tell me why there's a -- you have made a strong showing that --

MR. WILSON: Likelihood of success on appeal?

THE COURT: Right.

MR. WILSON: Yes, Your Honor. There's two broad issues. As I've already mentioned, one is likelihood of success. The other is irreparable harm. The Court's already asked a few questions on harm, but --

THE COURT: No. No. No, because I think I understood a lot of what I read, but I may not have, but at least there was one area where I knew that I hadn't actually understood what I read. So as you were up -- but yeah, let's get back to likelihood of success on the merits.

MR. WILSON: Yes, Your Honor. We believe there's two potential errors in the Court's memorandum opinion that are going to be of interest to the Federal Circuit. The first issue is that we believe the way the Court ruled on inherent disclosure of the efficacies is that that was based on one possible use of McDaniel's method as opposed to what's necessarily present which is the legal standard for something being inherently disclosed by a reference, in this case, McDaniel.

THE COURT: All right.

MR. WILSON: So that's one problem. And the other problem is the way that the Court used the concept of enablement is that the Court used enablement to supplement or add to what McDaniel disclosed, and effectively ruled as if the compositions that were disclosed 12 years later in Manetta was part of McDaniel, and therefore, that the efficacies were inherent in McDaniel. So those are the two issues that we believe are contrary to the law of the Federal Circuit and that we believe raises a substantial question on appeal.

I'd like to start, because the parties could not agree with respect to the legal standard --

THE COURT: Oh, I think I got that. Don't you think the legal standard is essentially -- I know this is your position, a strong showing that it's likely to succeed on the merits in the appeal.

MR. WILSON: We do agree that that's the standard except I would say that the Federal Circuit recognizes the sliding scale. In other words, where there's a clear showing of irreparable harm, the standard for the likelihood of success is lowered to a fair --

THE COURT: Was that disputed in your briefing?

MR. WILSON: Yes. Yes, it was disputed. Teva took the position that you'd have to show a strong

likelihood of success, not just on the appeal, but on all the merits.

THE COURT: No, but that's a different --

MR. WILSON: Different issue.

THE COURT: Yeah. Yeah. So that's what I was addressing when I -- yeah. I don't agree with Teva on that, so you don't have to really spend a lot of time on that.

MR. WILSON: With respect to how strong of a showing, I think the best case is Standard Havens. We've cited that in the reply brief at Page 2, and that discusses this sliding scale, and you know, introduces the idea that just a fair chance better than negligible chance can be sufficient if there's a strong showing of irreparable harm. And so I think that's a good case to give the Court guidance on how strong of a showing is needed on the question for appeal.

So unless the Court has other questions, there's a debate about which circuit controls, and we've cited revision history out of the Federal Circuit that says Federal Circuit law controls, not Third Circuit law. And so that's also in our reply brief on Page 1. That's binding on the Court. The Federal Circuit says that Federal Circuit law applies to the burden on likelihood of success, so we think those are the two cases that guide the Court in terms of the standard.

THE COURT: Okay.

MR. WILSON: So Your Honor, I'll turn to the Court's opinion and just kind of walk through my thoughts on what we believe the Court did wrong in terms of finding inherency in McDaniel.

And Ms. Chen, if I can bring up the -- I'm sorry. Yes, sorry, McDaniel.

So we're looking at the memorandum opinion, Your Honor, Document 257.

THE COURT: Yeah, I've got it.

MR. WILSON: And this is Page 2. And I think the Court's claim construction is irrelevant. This was the Court's -- there was debate at closing argument about whether or not the efficacy elements were limiting, whether they should be considered part of the claims for purposes of validity, and the Court made that decision in the memorandum of opinion here finding that all of the asserted claims require these method steps of topically administering, et cetera, and then separately stated that some of the claims require the efficacy. It made that statement two or three times in the memorandum, therefore, adopting Galderma's position that the elements about superiority metronidazole within two weeks --

THE COURT: So what you're saying is I agreed with you?

MR. WILSON: Yes, Your Honor.

THE COURT: Okay.

MR. WILSON: This opinion makes clear these are limited, and part of the claim for purposes of evaluating validity. I think the next relevant part of the opinion is to look at the findings of fact, and if we can go to Page 6 and look at the Court's findings of fact nine and ten which is on the screen.

This is the Court's findings, factual findings with respect to what McDaniel discloses as to the claim elements, and the Court made two findings. One was what was explicitly disclosed which was the method steps. Galderma disagreed with that and still disagrees with whether all those method steps are disclosed, including using one percent once daily and treatment of PPR and lesions. That's not relevant to the motion today, but the Court did find -- made a factual finding that all of those were explicitly disclosed in McDaniel.

And then I think the important one was to what we're arguing today in terms of likelihood of success is that McDaniel did not explicitly disclose the efficacies, and that they were inherently disclosed in the treatment method that was disclosed in McDaniel.

So when you have -- as the Court's aware, the parties have briefed it, what's required in order to show

that an element that's not expressly disclosed like the efficacy elements and in terms of the Court's findings what's required in order for that to be inherent. And I think there are -- as I went back through the briefing, I found three cases that I believe were illustrative of what is required in order to make a finding of necessarily present or inherency in this type of situation. They're cited in the papers, but I'd like to briefly discuss them.

The first one is a case called Purdue Pharma. This is cited in the reply brief. It's 811 F. 3d 1345. It's in their reply brief at Pages 5 and 6.

THE COURT: And you're talking about the reply brief on this motion or the reply brief back at the briefing on the underlying case?

MR. WILSON: Yes, Your Honor. This was cited in the reply brief on Tuesday --

THE COURT: Okay.

MR. WILSON: -- relating to this motion. And so Purdue Pharma was a case relating to a patent that covered a tablet, and the key element, the element that was discussed as being inherent was an element that said -- it talked about a certain type of dosage form tablet, and there was a wherein clause that's similar to the wherein clauses for our case. Wherein the dosage form had a breaking strength of at least 500N.

So we have an analogous clause where it's a performance wherein clause. Similar to wherein the method that's taught in our patents achieves these efficacies. And so if we can pull up -- this was the evidence that was introduced in that case relating to inherency.

So again, the element was: Did the dosage form have a breaking strength of at least 500N? And the situation in this case was there was a prior art patent that discussed how to make tablets, but did not disclose expressly that that method would achieve this breaking strength.

And so the defendant in that case actually had an expert perform testing, and it's described here in this footnote where they created thousands of tablets using the method of the prior art. And he actually testified at trial that to a -- every single tablet that was created according to the method that was in the prior art met the 500N element.

THE COURT: Isn't that essentially what your claims, which are results of clinical trials, and are percentages, and estimates, and things, isn't that the same thing?

MR. WILSON: Yes, it is similar in the sense of there is a wherein clause in the Jacovella patents, the asserted patents that require that the method achieve

certain efficacies. Absolutely.

But in this case, the defendant presented evidence that if you followed the equivalent of saying if I follow McDaniel thousands of times, I am 100 percent of the time going to achieve this wherein clause of this breaking strength. And that's what the Court relied upon that said if I go back and look at the prior art patent, I've performed testing, and I know through this expert's testimony that every time I followed that prior art patent, I'm going to achieve this wherein clause in a new patent.

And based on that evidence, the Court said that the evidence was without exception, every time they performed the prior art method, they achieved the allegedly inherent element of the patent. And the Court found inherency. But that gives you an example of the type of evidence that's necessary in order to say something is necessarily present.

THE COURT: Isn't the clinical trial evidence that you incorporate into your patent, doesn't that prove exactly that?

MR. WILSON: What the clinical trial proves is that the formulation that was tested in the clinical trials achieves these efficacies. That's what it says.

THE COURT: But it was good enough for the FDA to let you sell it; right?

MR. WILSON: Absolutely. It's good enough for the FDA to sell it. What it's not good enough for is to say the method that was disclosed in McDaniel is always going to achieve those efficacies. That's the question on inherency.

The question, as the Court found correctly, by the way, we believe, that none of the efficacies that appear in the Jacovella patents about superiority to metronidazole, statistical superiority in terms of relapse, statistically significant reduction of lesions at two weeks, okay, none of those were expressly disclosed in McDaniel.

And so the question for the Court on inherency was: Can I just take McDaniel, which doesn't disclose any of those efficacies, follow McDaniel, and no matter how -- what variations I use in following McDaniel --

THE COURT: Yeah, but see I don't think that's the right question. It's not every variation is McDaniel. It's the variation of McDaniel as claimed now as in your patent.

MR. WILSON: I disagree. I don't believe so. That's the thing on inherency. Inherency requires that what was disclosed in McDaniel inherently achieved the claims. It's not if you practice McDaniel according to the new patents, if you use the composition tested in the new patents, will that achieve the claims.

THE COURT: Well, see, that's where I disagree

with you because I think it's if you have a disclosure, a broad disclosure in McDaniel that then you divide it into ten slices, each of those slices which may produce different results. If you do that slice, it's inherent.

MR. WILSON: Right. And I believe -- respectfully, I believe that's wrong. I think that is the opposite of necessarily present. It can -- the case law is clear, it cannot be based on possibilities or probabilities.

THE COURT: No, that's the point is if you pick the ten percent, if you do the slicing, I don't think it's a possibility. I think you have basically -- you know, you have something that when you take that slice, you will get that result.

MR. WILSON: That is true of any obviousness case where you're going to combine it with a later patent and you say, I have these three elements over here. I'm going to combine it with another patent. And when I do that, I have all the elements. That's a combination.

Let me address the Armodafinil -- sorry about the pronunciation -- the next case I was going to discuss because I think it directly answers the questions you're raising, and this was cited. This is a Judge Sleet case.

THE COURT: Okay.

MR. WILSON: By the way, and if we could start on 465, this is exactly the question you're raising. It was

a method patent. And what Judge Sleet said is if the prior art here, McDaniel, can be practiced in a way that yields a product lacking in the inherent property, it does not inherently anticipate.

And so to go back to your example where there's ten slices, if one slice won't practice the patent, it's not inherent. It's not necessarily present. And if we can go to the -- to Page 469, the evidence in this case was interesting. There was evidence in this case. I think it's in the footnote 13. I'm not sure.

There was evidence in this case. There was declarations submitted during prosecution of the patent where there was a --

THE COURT: "In this case," you mean this case?

MR. WILSON: Armodafinil, the case we have on -- I'm sorry.

THE COURT: No. No.

MR. WILSON: Armodafinil, the case we have on the screen here. It's highlighted at the top of the page. There was evidence that -- so the prior art in this case was preparation one. Okay. I don't remember the name of the reference, but they refer to it in the case as preparation one. So that was the prior art.

And the theory by the defendant was every time I follow preparation one, I'm going to inherently achieve

what's in the asserted patent. And there was actually evidence in that case that it didn't submit it during prosecution that there was 34 experiments done following the prior art following preparation one. And 90 percent of the time, it achieved what was claimed in the new patent.

THE COURT: No. I understand that's not inherent.

MR. WILSON: Therefore, it's not inherent. And that's the same situation here. Here, we have Teva never even tried to say that every time you follow what you found to be expressly disclosed in McDaniel, one percent once daily to treat PPR, the factual findings you made with respect to what was expressly disclosed, there was zero evidence presented by Teva that said inevitably you necessarily will achieve the efficacy claims that you found to be inherent. Zero evidence of that.

In fact, Teva did the exact opposite. Not only did they not present evidence that that was necessarily present, they actually fought infringement for their FDA-approved drug. That's one-percent ivermectin used once daily.

They put experts on the stand that said not only is it not inherent, we don't think we infringe those efficacy elements. It can't be necessarily -- they can't, on one hand, say it's necessarily present, it's going to

happen a hundred percent of the time, and then turn around and put evidence on, and argue to the Court, We don't even infringe those steps.

The only efficacy element that they admitted they infringe was significant reduction. Every other element, they said they don't achieve.

Now, we disagreed with that. And there was evidence of infringement, we believe strong evidence of infringement of those efficacy elements. But my point is they didn't try to show necessarily present. And there's other evidence that we cited. If you look at footnote 12 in our reply brief, we cited testimony.

THE COURT: Yeah. You know, it's dangerous to rely on footnotes.

MR. WILSON: It is. I have a bad habit of using them, but --

THE COURT: Yeah, so I see.

MR. WILSON: In footnote 12, what we cited was testimony from their experts that's in the trial record.

THE COURT: Okay. It says footnote 12 of the reply brief. It says Teva brief at 7/8.

That's supposed to be helpful to me?

MR. WILSON: Well, let me find it, Your Honor. I apologize. I thought -- I thought it was footnote 12. Yes. We cited -- and I apologize for not having the

footnote correct. We cited the evidence -- let me see if it's in the motion. I apologize, Your Honor.

THE COURT: I mean, but it just goes to show why you don't capitalize your own footnotes.

MR. WILSON: Okay. I am correct, it's footnote 12. I have the wrong -- wrong document. It was actually footnote 12 in the opening brief, Your Honor.

THE COURT: Okay.

MR. WILSON: But we cited Dr. Amiji, Dr. Betensky, Dr. Gallo, and we asked these questions for a very specific reason, and that was to disprove anticipation by McDaniel. And we asked Dr. Gallo: Is every one percent applied once daily going to achieve these efficacies? And they said, I don't know. They declined to predict what would happen when you follow every step of what you found to be expressly disclosed in McDaniel.

Dr. Gallo said he didn't know. Dr. Betensky said she didn't know. Dr. Amiji said you would have to do testing, and then they contested infringement.

So that is the opposite of the evidence that I put up here in this other case that -- where they have an expert testify. I have done the prior art method, and every single time I do it, I achieve this wherein clause that was in the patent. And so that's the type of evidence that courts need in order to find something's necessarily

present.

The last case that I would point the Court to is the Braintree case which is -- it was a solution that had to be hypertonic. And basically the evidence that came out of trial was that was supposedly the inherent element that was not expressly disclosed in the prior art. And the evidence that came out is, I don't know, I'd have to test it to know whether it was hypertonic or not. And the Court said, Look, if you have to test it, and you can't tell me it's there a hundred percent of the time, that's not inherent.

So that is, I think, what would have been required. And the other thing that's important is that McDaniel doesn't disclose a composition. There's no excipients described by McDaniel that tells you this is the composition you use to treat people with ivermectin.

THE COURT: But the excipients, they're not disclosed. They're not claimed in your patent, are they?

MR. WILSON: They are not. They are not claimed. What's required is use of a one-percent ivermectin composition that achieves these specific efficacies.

So the composition is claimed in the sense that you have to use a one-percent ivermectin composition that is going to achieve all of the efficacies that are claimed.

THE COURT: You know, that strikes me as there's something else wrong with that.

MR. WILSON: Well, Your Honor, I would take a look -- we cited a case that Chief Judge Prost discussed, a very similar situation, and that is the *Allergan Sales v. Sandoz* case. It's 935 F. 3d 1370, and that's exactly what she found. There was a situation there where she concluded that there was no basis for assuming that all formulations of the claim combination behave like the brand drug. Since other compositions could be present in the composition, such as solvents, buffers, preservatives, that would not achieve the benchmark efficacies that were described in that case.

And so, no, there is no composition. You don't have to use specific excipients. What you do have to use is one-percent ivermectin composition once daily and achieve these efficacies. And so, again, that's a type of evidence we've seen, and there's no evidence in the record whatsoever that if you follow McDaniel's method, you're necessarily inevitably going to achieve the efficacies that are claimed in our patents.

So turning back to the Court's opinion, if we can go to Page 14, I've already discussed what I think the evidence would need to be in order to find inherent disclosure, but I want to talk about what the Court actually did because here this paragraph that's highlighted at the bottom half of 14, you mentioned that we argued, as I'm arguing today, that in order to meet the burden of

anticipation, they have to show that one-percent ivermectin formulation inevitably achieve these efficacies. I believe that's correct. I've cited the cases that I believe support that.

You said we cited no authority. Respectfully, I think we did cite that in the briefing.

But then what the Court did next I think is what's important because after rejecting that you thought that was what was required to prove inherency, you said to the contrary, it is well established that for a prior art reference to be enabling, it need not enable the claim in its entirety, but only enable a single embodiment.

We were arguing about inherency and what they had to show for inherency, and the Court went and applied the standard for enablement in which one adequate example is sufficient. That is the opposite of inherency.

So the problem is, yes, one example in a patent might be sufficient to enable, but that is not sufficient to find something necessarily present or inherent. And by the way, in the Court's inherency analysis in terms of finding that these efficacies are inherent, the Court didn't cite any evidence. The Court didn't cite any expert testimony, no witness testimony saying they didn't even try to present an expert that said, This is always going to happen when we follow McDaniel. You're always going to get these

efficacies. You're inevitably going to get these efficacies.

There was no evidence. That's why the Court didn't cite it. That's why the Court didn't cite it. Instead, they posited -- Teva posited this enablement theory which is flawed, and the Court adopted it. That's what happened.

They presented this enablement theory. That's what the Court used. The Court didn't cite any evidence on inherency supporting the idea that it's necessarily present.

I do think that there's a separate issue, as I mentioned earlier, and that is using Manetta and injecting it into McDaniel. If we go up a little bit on Page 14, please, this is where the Court gets to inherency, the only remaining issue. And the way the Court phrased it was the only remaining issue is whether McDaniel discloses using the same formulation.

Okay. And then down below, you talk about enablement and the fact that there's a stipulation that Manetta is one of formulation that enables McDaniel. Enablement allows a piece of art to be -- to qualify as anticipatory prior art. It does not change what McDaniel discloses.

And the way the Court wrote the opinion, the Court through enablement made the conclusion that enablement

injected the Soolantra formulations into McDaniel, and then said, well, now the efficacy is based on what the Court concluded about the express disclosures, said if you use Soolantra, one percent once daily to treat PPR, you're going to achieve these efficacies. That's changing the fundamental disclosure of McDaniel. That is not proper.

And so I think both of those -- basing it on possibilities instead of what's necessarily present and then using enablement to basically supplement what McDaniel says, and then find inherency, I think both of those are issues that the Federal Circuit may disagree with. And again, the Court doesn't have to today decide that it agrees with me on these issues. What the Court has to decide is there is a fair question, there's enough of a question that the Court should stop the generic activities so that the Federal Circuit can make a decision on whether the Court agrees with Your Honor's opinion.

THE COURT: All right. Thank you, Mr. Wilson.

Why don't I hear from Ms. Ben-Ami about this rather than from Mr. Alibhai about the irreparable harm.

MS. BEN-AMI: We do have some slides, Your Honor. May I proceed, Your Honor?

THE COURT: Yeah.

MS. BEN-AMI: I believe counsel just told you an incorrect view of the law. If I have a patent and say in

any case, and in that patent, I have three examples, and one of them meets every element of the claim except it doesn't say something that's inherent, and let's assume we agree that that is inherent, the fact that the other two examples don't meet that is irrelevant. If you have an example that meets every element explicitly or inherently --

THE COURT: I mean, I'm not sure that Mr. Wilson would actually disagree with what you're saying right now.

MS. BEN-AMI: I think that is what he said because he's saying you have to say inevitably everything is going to work, no matter what and that --

THE COURT: No. Well, what I interpreted him to mean is if you say one percent to five percent once or twice daily, I guess what I thought he was saying is that's a range of options, and you would have to work at one percent. It would have to work at five percent.

MS. BEN-AMI: No, Your Honor. I don't believe that's what Mr. Wilson was saying.

Mr. Wilson, were you saying it has to work at five percent?

MR. WILSON: Do you mind if I --

MS. BEN-AMI: Go ahead.

MR. WILSON: -- step up here? I'm sorry. I think the issue on whether or not a different one percent composition will work is about the composition. The

testimony at trial that we got from Dr. Amiji and Dr. Betensky was the issue of if you change any excipients, they don't know if it's going to work.

MS. BEN-AMI: That's different.

THE COURT: Okay. But that seemed like -- well, so maybe you're right.

Ms. Ben-Ami, in any event, go ahead.

MS. BEN-AMI: So can we have Slide 24? This has been rejected by Courts. If you look at *Schering vs. Geneva*, Federal Circuit case, and an anticipatory reference need only enable subject matter that falls within the scope of the claims at issue, nothing more.

THE COURT: And we think in that sentence that enable means disclose?

MS. BEN-AMI: Yes, enable subject matter. And if we look at Slide 23, going backward, but I'm trying to address, this is a case where Galderma stipulated to something, and they have tried to back pedal from that at trial and now here in court.

And this is what was said at a deposition to get me to stop asking questions of Dr. Webster. They were agreeing that Manetta enables McDaniel in 2012 as to the claims as well as everything that it taught as to the formulation.

So now they're saying that when it says you can

make a formulation with sufficient penetrating agents that it will work. That is enabled by Manetta. Manetta has told you it will work.

And so if we look at, say, Slide 21, let's look at claim 1 of McDaniel. McDaniel says a method of treating rosacea orally administering or topically, et cetera, et cetera in a dose sufficient to fill and eliminate the Demodex mites. Resulting, they're saying there's a result. Resulting in cessation of the manifestations of the allergic and vasomotor responses to the organism that causes the symptoms and signs of rosacea. It is a claim to a method of treatment getting a result. And that is explicit.

And in the specification, and you cited this several times, Your Honor, this part of the specification on the right where it says the clinical signs of these bad things happening from the Demodex are papules and pustules. So where it says the clinical cessation of the manifestation that caused these clinical signs, it's saying method of treatment, topical, resulting in cessation of what is causing these clinical signs ending the papules and pustules.

That is enabled. They have admitted it works. They've admitted, and now they come back and say, but not every -- you could make a formulation that doesn't work.

But you take what is explicit in the patent and

now you say, is something missing? Here, what they were saying was missing was a specific formulation. And then during the deposition, they say, No, we're not going to argue that. We're going to argue that -- we're going to admit that the formulation element in the claims is enabled. And if that formulation element in the claim is enabled, then everything that is taught in that claim works. And that claim says you're going to reduce papules and pustules.

There is a resulting feature in that claim. So what we have here is a situation where -- and we can go through the other claims, and I'm not quite sure what claim we're even arguing about because, as far as I can tell, the only claim where there's an admission of infringement, I'm sure of this, is claim 6 of the '118 patent. And claim 6 of the '118 patent, the only thing it says is broad, any topical, one percent, about one percent. So it's even broader than that, and it says resulting in a significant reduction of lesions which could be one lesion out of a hundred, and it could take two years. It doesn't matter.

This claim says the same thing. It says the same thing. Originally, they said, Oh, but you don't have a formulation that specifically says that it will do that. Then they said, No, we agree the formulation is enabled by Manetta.

So when we look at McDaniel, claim 6 is gone.

Claim 6 is gone because claim 1 includes the same things. And then when you go down to claim 5, it tells you it can be a carrier lotion, a cream, or a gel just like the '118 patent tells you that. And then it says at least once or twice daily for a period of about two weeks. It tells you that.

So all the elements that we're talking about, and in the specification it tells you it's going to work better than metronidazole. I don't know why we have to talk about all of these elements. But certainly, certainly what was the purpose of making this stipulation? On Page 23, please.

THE COURT: Well, I think you said the purpose is to stop you from asking Dr. Wilson questions.

MS. BEN-AMI: Dr. Webster.

THE COURT: Webster.

MS. BEN-AMI: Yes, but I said I want to make sure we have a real stipulation. You're agreeing that Manetta enables in 2012, enables the claims. And if the claims are enabled, then that means when you read that claim and it says it's a method of treating, it's going to get these results. That's all you need.

THE COURT: But the results that are disclosed in McDaniel are not as precise or specific as the results that are in the Jacovella patent; right?

MS. BEN-AMI: If we look at Slide 21 again, the only thing in this claim is that it says obtain a significant reduction of inflammatory lesion count.

THE COURT: Well, you're talking about claim 6, but there were other claims, too; right?

MS. BEN-AMI: There's no other claim where there's a finding where there's infringement.

THE COURT: No. No. I understand your point, but after all, I invalidate all the claims, not just claim 6. Are you saying, yeah, you can't really speak as to whether the rest of that invalidation is any good?

MS. BEN-AMI: Oh, no, I can. I just didn't necessarily make slides for everything else because this is a motion on whether it is providing an injunction. And for an injunction, you need infringement and validity. Right. You can't have -- if you have validity and no infringement, you can't enjoin.

So in the patent in the specification, and I don't know if we still have that slide, it says that it is better than any prior treatment. And then when it says it's better than any prior treatment in the example with the three patients, Slide 20, you have Slide 20 where it says that the patients were given metronidazole topical which failed, and now they succeeded with the oral ivermectin.

And you'll recall the next paragraph, it says,

and now topical is included as well, and you just have to use enough permeating agents for it to work.

THE COURT: So Mr. Wilson said a bunch of things, some of which I think I've heard before. I saw in the briefing, some of which I was not so sure about. So one of the things that he said now was something like the formulation is limited by the results of your claim.

Do you have any comment on that? First off, do you understand my question?

MS. BEN-AMI: I think what he's saying is, and this was our written description argument which is an alternative ground, right. What he's saying is -- let me go to Slide 22. Maybe that will help.

I want to just go back a little bit. There's only one formulation that was ever tested, one clinical trial formulation. The patent here does not teach which formulation it was, and I'm talking about the patents-in-suit. Rather, they said there are four examples of Manetta, and they all work.

So what did we just learn from that, that without testing they can tell you that three examples in Manetta that were never tested will work as well. So we have that -- like the tablet case, you know, with here, they're saying we know that this is going to work, and there are four examples.

Now, then they said, but you know, we can't tell you that you need to use this excipient to go ahead and make it work, or that excipient to make it work, or you know, boil it at this temperature, or that temperature, whatever it is. But that doesn't matter because the claim only claims the things that work.

THE COURT: Yes, that's what I think he just said.

MS. BEN-AMI: Well, you go back to McDaniel, the same is true. The claim only claims the things that work. The claim says I'm claiming that the thing, the method wherein you get the results. I'm claiming a method where you can use it once daily. I'm claiming the method where it's better than metronidazole. I'm claiming -- so it's the same.

If we look at this, if we look at the difference between the two things, they claim broadly -- remember, they have claims to a Soolantra formulation. We don't infringe those. So the only way they can attack us, they would -- they would argue that we infringe Manetta, which they don't.

So here they've gone ahead, and they've expanded, and they say, It doesn't matter that we don't teach you all these different ways to do it because all we do is you test it, and if it works, then it's in our invention. So both broad disclosures, both claim results,

both disclose results that this is what you want to get, and it has to be the same for both patents.

The reality is that the McDaniel patent teaches that it's better than metronidazole. If you look at Slide 20 in these examples of these patients, it says they failed on metronidazole, then they succeeded.

Dr. Gallo testified that these were three for three, that shows that they're statistically significant. Remember that it doesn't mean it's a big difference. We have to remember what significant in these claims mean. Significant in these claims means it's not by chance alone. That's all it means. That's all it means. It doesn't mean it's ten times better, or a hundred times better, or one percent better, or two percent better. It just means that it works.

THE COURT: So let me ask you a question, Ms. Ben-Ami, because I have to say that you seem to be all over the map without actually addressing what Mr. Wilson said.

Did I get something wrong in the opinion?

MS. BEN-AMI: No. No. And I think if Your Honor looks at the Ben Venue, the BMS v. Ben Venue case, the second part of the anticipatory, there's two groups of claims that anticipated. And you go through that, you're right on point. If you look at Schering, it tells you if

you have one example that's enabled, it's right on point. If you look at Perricone, Perricone --

THE COURT: Well, I thought Perricone was the case.

MS. BEN-AMI: Perricone is the case. Perricone says if you're doing the same exact method, then that's it. And so what they're trying to say is if a patent tells you that you can make formulations that work, and then -- but there might be a formulation that doesn't work, the part that says you can make formulations, that work is irrelevant, and that's not the law. That's not the law at all.

If I go back to this, let's imagine there was an example, one example in writing. Right. As in McDaniel, it says you can make this, you just put in enough penetrating agent so that it's going to work. Right.

If there was another example that didn't work, would that mean there was not anticipation? Of course not. There's anticipation. And so I don't mean to be not responding to him because I'm trying to respond to you.

So where we are here is once they admitted that the formulation was enabled, it means that everything that McDaniel teaches is true. And when it's true, you have to accept it that all those things naturally flow from it. So therefore, there is a formulation that works. Therefore,

that formulation is disclosed to get these results. Therefore, that formulation is disclosed to tell you that it's better than metronidazole. All those things come through.

And when you have a formulation like Manetta, which in 2012 we're looking at what was in the public domain in 2012, not in the 2002. When you look at 2012, and you say what is in the public domain, you have McDaniel which has been enabled by Manetta, and you will get these results because it's the identical method.

THE COURT: And the point of saying Manetta enables McDaniel is McDaniel. As a patent, it's presumed to be enabled when it was issued; right?

MS. BEN-AMI: Correct.

THE COURT: But the thing about Manetta is that it discloses a particular, I don't know, formulation that you can make that, or saying Manetta enables McDaniel, what does that actually mean to you?

MS. BEN-AMI: What it means to me is it's an acknowledgement that in 2012, a person skilled in the art reading McDaniel would be able to practice McDaniel and achieve all the results.

THE COURT: And how does Manetta help in that regard?

MS. BEN-AMI: Because Manetta was shown to

obtain the results, and Manetta is a -- it falls within McDaniel.

THE COURT: I'm sorry, it falls within?

MS. BEN-AMI: McDaniel. Manetta is a formulation of one-percent topical ivermectin that can be used. As they said, enables the formulation. So it says if Manetta is a formulation of one-percent ivermectin, that can be used, and that formulation has been proven through clinical trials to meet each and every element of the '118 patent.

THE COURT: And the '118 patent is which one?

MS. BEN-AMI: The patent that we're no -- the '118 is the patent-in-suit.

THE COURT: The '118 patent. Sorry.

MS BEN-AMI: Right. So when they say Manetta including -- it says enables the formulation, enables the claims. They're saying Manetta is a formulation that fits in the claims that will inevitably, inherently every single time work. It has to work because their clinical trials said it has to work.

Well, it's different than them saying, you know, we're no longer going to argue that it's not enabled, or we're going to admit that it's enabled. They said by Manetta for the formulation and including the claims.

THE COURT: But what you're saying is the

stipulation says -- I'm not sure that I'm following what you're saying right now. The Manetta is a formulation, McDaniel is a method; right?

MS. BEN-AMI: McDaniel is a method with a broad disclosure of formulations by saying you can.

THE COURT: And Manetta is?

MS. BEN-AMI: Has specific examples of formulations.

THE COURT: And so normally when you're talking about anticipation, you're talking about the McDaniel, whatever is disclosed in the 2002 understood by person of ordinary skill in the art expressed and or inherent, and because it's a patent is presumed enabled, but could be challenged. And so by saying Manetta enables McDaniel, are you saying Manetta is disclosed in McDaniel?

MS. BEN-AMI: I'm saying Manetta is a formulation of McDaniel --

THE COURT: And --

MS. BEN-AMI: -- which necessarily will work.

THE COURT: Is a formulation that's described in McDaniel?

MS. BEN-AMI: It's encompassed within McDaniel. And when they say it enables the formulation, they're saying that Manetta provides a formulation that will work.

MS. BEN-AMI: And in 2012 -- I'm sorry.

THE COURT: No. So McDaniel says, you know, do a method, use one, or two percent, or five-percent topical ivermectin cream. Then Manetta comes along, it has a more specific formulation, and the use of the verb enable to connect Manetta to McDaniel, does that mean that a person of ordinary skill in the art following McDaniel would in some sense -- I was going to ask you, but in some sense would then, you know, without undue experimentation make the Manetta formulation, or does it have nothing to do with that kind of enablement?

MS. BEN-AMI: Oh, enablement is different in the sense of anticipation, and it's slightly different. Yeah, it doesn't mean that. It doesn't mean 112.

THE COURT: Right. Well, so that's what I'm just trying to make sure that I understand which is enabled, the way you're using it, is the same as disclose?

MS. BEN-AMI: In effect, yeah, because he says as to the formulation, he says as to the claims, as to the formulation. So when you -- and maybe that's where defendants are -- enablement for anticipation, enablement, 112 are different things.

So when we look at this, you have a broad disclosure in McDaniel. McDaniel says you can make one percent, and I don't think we need to worry about that. He also says is two percent, or three percent, or five.

THE COURT: Yeah.

MS. BEN-AMI: So he says you can make a one-percent ivermectin topical that can be used once daily and that it will get these results. Right. It says it will be, and we have to accept that. That's an explicit disclosure.

It will get that result. It will be better than metronidazole. It can work in two weeks. Those are explicit disclosures in the patent.

THE COURT: In McDaniel?

MS. BEN-AMI: In McDaniel.

THE COURT: Okay.

MS. BEN-AMI: And now you have a disclosure by Manetta saying you have -- that it's one percent, et cetera, et cetera, et cetera. And you can get all the results that a one-percent ivermectin topical will give. And when you look -- it's very important. I would really love to go through McDaniel again because it's been a while, but it's very important to realize that McDaniel teaches a lot. McDaniel teaches a method of treatment resulting in a reduction of papules and pustules.

THE COURT: So let me just go back. A person of ordinary skill in the art reading McDaniel, does McDaniel teach them the Manetta formulation?

MS. BEN-AMI: It teaches them one-percent

ivermectin formulations that work.

THE COURT: Okay.

MS. BEN-AMI: And that includes -- so does it say two percent of this or two percent of that? In 2002, no. But in 2012, a person skilled in the art, what did they know then? What did they read?

And this is not obviousness. This is not obviousness. They know that McDaniel says one-percent ivermectin will work, will get this result of lowering papules and pustules. And they say, okay, what a POSA has available to him is formulations that will get you there. It works. And that's what Perricone says, and that's what Bristol-Myers versus Ben Venue says. It says as long as there's enabling disclosures, that's enough. That's it. That's all it says.

And so what's happening here is that -- I don't know that we have time to go back through all of McDaniel, but I mean, if you go back through McDaniel, he says, This is my theory. I am telling you that if you put on topical ivermectin one percent under these --

THE COURT: You'll get the results.

MS. BEN-AMI: -- you're going to get the results. Right.

That should be enough, to be honest with you, Your Honor, for anticipation. But furthermore, in 2012,

they have admitted that that formulation element is enabled, that a person can do it using Manetta. And so a POSA reading that at that time has all these teachings, and it has a further enabling disclosure by Manetta per Perricone and Bristol Myers, and the other cases that say it works.

And there is this body of case law which you cited, and that body of case law stands for this proposition. And all they're arguing now is, and it's hard to hear what they're arguing now is one could make a formulation that would not work. That would be true for McDaniel, but it wouldn't meet the claim. That would be --

THE COURT: I'm sorry. It would be true for McDaniel, but it wouldn't be what?

MS. BEN-AMI: Right. You can make a formulation of one-percent ivermectin that won't work, but it wouldn't meet claim 1 of McDaniel because it's supposed to be resulting in the cessation of the -- to get -- it says resulting in getting the results. You could make a formulation under claim 6 of the '118 patent that doesn't work, but as Galderma has said, the claim requires that it works. And therefore, the only formulations that are within the scope of the claim are the ones that work. These two are identical. These are identical.

If you look at claim 6, it can be any formulation of one-percent ivermectin as long as it gets a

result. One pimple out of a hundred over two years. When you look at McDaniel, it's the same. Look at the claim except it has one percent in the dependent claim.

They're the same. They use different words because he's saying you do it by killing the mites, but he says putting it on the affected skin, which Your Honor has already said includes papules and pustules, resulting in the features that cause the papules and pustules. And then in the spec we've looked at, and he gives you examples where he proves that ivermectin works, and then he says the topical will work the same.

So when you have a broad claim like this, and we have to remember we're talking about anticipation of a claim, right. If you have a broad claim like this that doesn't require any specificity of formulation, and I am talking about claim 6 of the '118, if one example of Manetta enables that, they've admitted it's similarly McDaniel. They've admitted that. They've admitted it.

And so if you go back and look at Bristol Myers, and I'm talking about there are two sets of claims. The second set of claims, if you go back and look at Perricone, if you go back and look at the art Schering, if you go back and look at all the cases you cited, they stand for this proposition. If there's one -- and I can take you through metronidazole. I can take you through the others, but I

don't think it's necessary because there's only infringement in claim 6. And when we look at claim 6, look how broad it is.

THE COURT: All right. So thank you. Let me just hear from Mr. Wilson again for a minute.

MR. WILSON: Your Honor, I was listening closely and Ms. Ben-Ami is taking you down the exact same path she took you in closing, and I believe it is error. What she is saying, you asked her specifically is enablement the same as disclosure, and she said yes.

That is exactly what she's doing wrong. She's saying if something is enabled, that means it's disclosed. And as the Court just pointed out, every patent is presumed enabled. If all you had to decide was is the prior art enabled, and therefore, you know, it's anticipatory, that would be anticipation. All enablement means is that McDaniel gets credit for saying you can make a gel, cream or lotion.

When we stipulated to enablement of McDaniel, we had previously taken the position that because McDaniel didn't tell you specifically how to make a topical gel, cream, or lotion, it wasn't enabled. You wouldn't know how to make one. And we decided, talked to our experts, that's not true. You would, as of 2012, know how to make a formulation.

At that point, it's enabled. It gets credit for disclosing broadly using a gel, cream, or lotion. That doesn't mean it discloses Manetta. That is a combination that requires obviousness. And all the things that go along with obviousness, expectation of success, secondary considerations, et cetera, the Court decided not to address obviousness.

The question on appeal and the question for today: Is there a fair question for the Federal Circuit? And the question that's going to be presented to the Federal Circuit is what she is saying now, which is if it's enabled, it discloses Manetta. That is fundamentally wrong. There is no support for that, and I believe there's a likelihood of reversal of that issue.

I will also point out, and I think this should be a very strong sign of whether or not there's a substantial question, multiple times during the argument just now she went back and argued that McDaniel expressly discloses the efficacies. They did that in their response brief, too. I was stunned.

They argued the decision by the Court was that they were not expressly disclosed, the efficacies. By the way, it's not just that it works. The Court knows this. It has to have significant reduction at two weeks. It has to be statistically significant, superior to metronidazole. It

has to be statistically significant in terms of relapse. It's not just that it works.

THE COURT: Well, the disclosure for the broadest claim, you know, to the extent the argument is McDaniel expressly discloses the broadest claim, maybe that's an argument you can make or not. I think part of the reason why I heard so little about it in the other claims is saying it gets good results can't really expressly disclose a lot more specific things that are actually claimed in some of the other claims.

MR. WILSON: Teva is trying to change the Court's opinion to express disclosure. That's what they did in their response. They spent two pages trying to argue how McDaniel expressly discloses the efficacy elements of the Jacovella patents. The factual --

THE COURT: Well, today it was concentrating on claim 6.

MR. WILSON: She's focusing on claim 6 intentionally. The other claims are much more specific, very, very specific benchmarks.

THE COURT: Yeah, what I just said is if you're going to argue that, that's the best claim to argue it for.

MR. WILSON: Absolutely. And that's why they're trying to change the standard to have to prove, you know, the entire case, and that's why she's saying you only have

to worry about claim 6 because that's the only one they stipulated infringement to.

The question is: Is there a chance of reversal of your opinion? And you entered an opinion that invalidated all the claims. Is there a substantial question, a fair question for the Federal Circuit on that issue? And Ms. Ben-Ami getting up here and saying enablement equals disclosure, your specific question is wrong, that is not the law of enablement.

All we were agreeing to is the McDaniel, yes, in 2012, you would know how to make a lotion, cream or gel. There's lots of ways to make a lotion, cream, or gel. Their expert said they don't know whether those other ways will achieve these efficacies. They don't know whether it's inevitable and necessarily present in every one-percent ivermectin formulation, and they contested infringement. Not just a bad formulation, an FDA-approved formulation.

Teva has taken the position do not meet the claimed efficacies. That is not inherency. That's the opposite of inherency.

So the ultimate question in front of the Court is: Is there something that the Federal Circuit could disagree with? And the Court's conclusion was only inherently disclosed based on enablement. No citation to evidence at all on whether it necessarily achieves that.

That is a fair legal question for the Federal Circuit to decide, and then the result is if you believe that's a fair question, if the Court does not issue an injunction now, and the Federal Circuit agrees with Galderma, the damage will be permanently done and irreparable. It cannot be reversed.

THE COURT: Okay. Thank you, Mr. Wilson.

MS. BEN-AMI: Your Honor, can I respond because --

THE COURT: I don't think he said that much, so --

MS. BEN-AMI: Just as to one point, Your Honor?

THE COURT: All right. One point.

MS. BEN-AMI: No slides. No points. They're asking you to enjoin Teva.

THE COURT: Yeah.

MS. BEN-AMI: That's why we're here.

THE COURT: I got that.

MS. BEN-AMI: Well, to enjoin Teva, doesn't there have to be infringement? There's only one claim where there's a finding of infringement because we stipulated to it.

So no, the question isn't here about whether a battle about all the other claims because they're asking you today to take Teva's product off the market, to have it lose

its 180-day exclusivity, to allow --

THE COURT: Okay. I've got your point.

MS. BEN-AMI: Right. I mean --

THE COURT: Thank you. Please sit down.

Mr. Alibhai, how are you doing?

MR. ALIBHAI: Good afternoon, Your Honor. I wanted to address some of the issues about irreparable harm that the parties have addressed back and forth.

THE COURT: Yeah. You know, I'll let you tell me what your biggest point is, but you know, my general take on it is that there's, to quote Mr. Wilson, a sliding spectrum of how hard it is to figure out what the harm is from an infringement or from being on -- well, from infringement.

And you know, I read what the comments said, both sides. I appreciated the professor, the MIT professor's graph somewhere in his reply declaration. I think he probably has it roughly right, but you know, all the time in infringement cases, you're usually -- all the time, you've got some period of time that's in the past, and you're trying to figure out what that's worth, and you have some period of time in the future, and you're trying to figure out what that's worth. And it's really just a question of how difficult to do it is. So that's one thing.

And then the other thing is, you know, you've

got a 170-person Galderma unit that sells things. They won't be needed. You know, Teva is going to have some group, maybe it's 170 people. It will be fewer because they're a generic that will be trying to sell things and fill orders. You know, it's pretty fine distinctions.

So it seems to me that your better argument is what Mr. Wilson was saying not what your economists are saying. But with that in mind, go ahead.

MR. ALIBHAI: Well, I'll start with the first argument which is, Your Honor, I think Mr. Wilson today laid out an excellent case of why there's a fair question, a substantial question of --

THE COURT: Okay. But he did a fine job without you repeating it.

MR. ALIBHAI: And so the point is that what's the question of the irreparable harm and what's the harm to Teva versus what's the harm to Galderma. The only harm that's been identified by Teva at all, as I read through all the papers and the declarations, was that they're going to lose their 180-day exclusivity. That's all I saw, and the response to that is that has been contractually protected by virtue of the Perrigo agreement.

And so the way this works is if the Court enters an injunction today, and then we go up on appeal, and somehow the Federal Circuit affirms and the injunction goes

away, Teva can go and launch again. And during --

THE COURT: So I am correct in thinking that if I were to enter an injunction today, one thing that I'd be doing is requiring you to post a bond of like a million dollars a day or something to cover them down the road in case I wrongly entered the injunction; right?

MR. ALIBHAI: Well, it wouldn't be a million dollars a day. This is a market that has net sales of approximately 90 million a year.

THE COURT: All right.

MR. ALIBHAI: And all --

THE COURT: So $250,000 a day?

MR. ALIBHAI: Well, it wouldn't be that much. Again, we can talk about the bond, but it wouldn't be that much because they are not losing that money. They're going to have the right to go get that money in the future.

So what would happen -- and yes, a bond is one way to protect any harm that we think may exist to Teva, but let me explain why there's no harm at all. The reason is that if the Court enters an injunction today and they can no longer sell their product, the authorized generic will be removed from the marketplace.

Perrigo will not be able to enter the marketplace by virtue of paragraph 5B of their license agreement with Galderma.

The case will go forward on to an appeal. The Federal Circuit will decide. Let's assume worst-case scenario for Galderma that the Federal Circuit affirms completely, and that's a final decision. Forget whether the Supreme Court reviews it or not. They can launch at that time.

By virtue of paragraph 5B of the Perrigo agreement, Perrigo cannot go to market until 181 days after Teva's been on the market. So that 180-day exclusivity has been built in contractually to the license agreement between Galderma and Perrigo. And there is no other ANDA filer that we're aware of, and no other ANDA filer would be able to get to market in the next year any way even if one came along later.

So the only harm that they argued is this 180-day exclusivity issue. Not only will they have their 180-day exclusivity sometime in the future, if they're right, they've also made money off of the last two weeks and whatever sales they've been able to accomplish because they have presumably flooded the market. So they'll get two chances to get to the marketplace.

And what Mr. Gambino and Dr. Hausman will talk about is that Soolantra is a new product. Right. It came in 2015, had growth every year. When they get this marketplace in a year, it will be even stronger than it has

been the year before.

THE COURT: I think the growth over a year, isn't it -- I don't remember the general trend. It was not predicted to be much this year. It seemed like the price was rising faster. So the growth is not actually like number of units sold, it's just more profits because you're charging more; right?

MR. ALIBHAI: I think it's both. I think it's the revenue. There's price increases as well as growth in that marketplace. Today Soolantra is approximately -- has about 16 percent of the rosacea market treatment, even though there's all these generics and all these other things out there, and it's the number one branded.

As the Court will presumably remember from the trial, this was the number one branded drug for rosacea. It's Finacea. One of them went generic. There's another Finacea product, but this is the one -- number one brand. So this is a graphical representation of what that market has looked like every year, and it's projected to beat this year what it did last year.

And so the point is that's the harm to Teva. We've shown how that harm will not come to fruition both because of the contractual agreement, both because this is a growth market, and there's a good market there.

On the other side, there is actual tangible harm

to Galderma. The first is what the Court talked about, an entire set of people whose job it is to promote this product, to create information about rosacea. That treatment will be laid off, will lose their jobs, and will not be able to do this job anymore because Galderma will not have a need for them to do that job anymore.

THE COURT: When are they going to start being laid off?

MR. ALIBHAI: I think it depends on what happens with these injunction and proceedings here, and if necessary, at the Federal Circuit.

THE COURT: So I take it in the last two weeks, nobody's been laid off?

MR. ALIBHAI: No. We're hopeful that the Court will enjoin them so we have not laid anybody off.

The second irreparable harm that's not addressed by Teva, and they had a copy because Your Honor ordered the production of the Perrigo agreement, and it went out that day.

THE COURT: Yeah. I could tell that they had it.

MR. ALIBHAI: If the Court does not enjoin Teva today and the appeal goes forward, in approximately 165 days when their 180-day exclusivity expires, Perrigo will be able to launch their product. In the event that the Federal

Circuit reverses and the case is remanded back to this court, and Your Honor or a jury determines that there was infringement, and the patent is valid on the other arguments that they made and their potential damages against Teva, what will never happen, what will never happen unless this Court issues an injunction is that Perrigo will stay on the marketplace because nothing stops Perrigo from going to market 180 days -- 181 days after Teva goes on the marketplace without an injunction.

And that's an important provision in that paragraph 5b. There's two paragraphs in this.

5b, the second paragraph says that if the Court enters and if we seek an injunction, and an injunction is entered within that 90-day period, the question you were asking was, the 90 days, is it enough time to allow the parties to move for an injunction and for the Court to have the time to consider and grant one.

If it happens in that 90-day period, then it's a complete reset. It says if there were no launches, if there was no activity by the first filer --

THE COURT: Yeah, that's what Mr. Wilson said.

MR. ALIBHAI: Right. And so there's another set of harm that will occur if Teva's not enjoined is that Perrigo will go to the marketplace. And even if we're right, even if the Federal Circuit reverses, that's

something that we won't be able to fix or remedy. The marketplace will still be dominated by generics. Even if Teva's removed at some point, it will be a year plus from now, even if we're able to get damages from Teva, that will not affect our ability to go after -- there will be no damages from Perrigo.

And so that's irreparable harm. And given just those two things, Your Honor, I think that both the fact that Perrigo can go into the marketplace and that there's a number of people who would lose their jobs over this, and combined with the questions we've raised, that's sufficient to enter an injunction to preserve the status quo which was the Court issued an opinion regarding one argument that was made, and that we believe has questions that should be addressed and allow that question to be addressed.

And given that they would suffer no harm during that time other than the loss of exclusivity that they're just going to push forward, it's not a loss, they're just going to have that right if they're right. If they're not right, they won't get their exclusivity, they'll just get the money that they made over the last few weeks.

And so with respect to the issues that they raise, they talked about the authorized generic, and they talked about the delay. You know, I was surprised when Ms. Ben-Ami told Your Honor that they were surprised that we

filed a motion. If you saw the evidence, you didn't mention my declaration, but there was a declaration by me.

THE COURT: I did, you know, and I don't mean this in the context of you personally, but when I get a bunch of affidavits, the least important one to me is the one that's signed by the attorney.

MR. ALIBHAI: I understand that it is, and that's why I attached the emails to show Your Honor.

THE COURT: And I did see that it was the back and forth. I was just less interested in that.

MR. ALIBHAI: Well, and I bring that up because they try to make this argument about delay. They knew full well that we intended to seek injunctive relief if necessary. We were not aware that they were going to launch. They were not going to tell us. They did not give us notice, and at no point did they tell us in the second case in which we've served discovery that, by the way, we know you've asked before, we're going to do this. If you want to move for an injunction, go for it. If you want to expedite briefing, we should discuss all that.

They decided to put themselves in the situation. Judge Robinson and other judges have said you risk your own 180-day exclusivity in that situation in the In Re: Cyclobenzaprine case. But again, not an issue here because contractually their exclusivity is protected between

Galderma and Perrigo's agreement.

The market share argument is an important one here as well, Your Honor, because while we do talk about damages, and we talked about the chart that Dr. Hausman has on Page 10, I believe, of the affidavit, the declaration, this is a very crowded marketplace. And there's generic metronidazole. There's a Finacea product that's generic. There are doxycycline products. There's Oracea which is an oral product sold by Galderma as well.

And one of the things that will happen is there will be all kinds of movement in this marketplace between products if there's not an injunction issued because people will be changing around, buying different things, and it will be impossible for us to know where we lost that market share to. Because it's not binary that it's just Galderma and Teva out there, it will be Galderma, Teva, and Perrigo out there.

And in addition, there will be all these other things out there. Dr. Hausman was the expert in this Plavix case, and in the Plavix case that Mr. Hofmann refers to, Plavix had 91 or 92 percent of the marketplace.

THE COURT: Yeah. I mean, I saw the Plavix thing, and that seemed to me that was just, for lack of a better word, a data point that was out there. I mean, you know, and to some extent, too, I think when you have the MIT

guy, you know, when there's this study that shows this and this study that shows that, and you know, and to some extent, the study may be more important than what happened in Plavix. But you know, the just pointing to random examples where things happened doesn't really strike me as having much persuasive value.

MR. ALIBHAI: And I think if we look at the situation based upon the evidence that was presented at trial is that, like I said, this was a crowded marketplace.

THE COURT: Yeah. Yeah. No. No, but I do believe that. Yeah.

MR. ALIBHAI: And so looking at this situation, there's going to be a loss of market share for Galderma, and it's going to be impossible to quantify what happened to that market share at some point in the future. And I think that's what Dr. Hausman, the MIT professor, is talking about is that when it comes to future damages, and you try to figure out where would you have been had there never been this entry by Teva in the event that the Court finds that it was improper, then how do you determine what happened to your market share based upon what happened because of Teva, what happened based on Perrigo, what happened because of metronidazole, or other many drugs that are in this marketplace. And that's the type of harm that, because it's impossible to quantify and because there's no way to

determine the damages for that future harm, is considered irreparable harm. And the Federal Circuit's definitely said that erosion of market share is one of those types of things.

The other thing that we haven't talked about is price erosion. It is undisputed that there is a drop in prices when generics come into the marketplace. And when two generics come into the marketplace, which is what will happen in 165 days when Perrigo enters the marketplace as well if there's no injunction, is that there's going to be Teva and Perrigo competing with each other. And in order to compete, they're going to have to offer the lowest price possible in order to get a pharmacy or distributor to choose their product, especially over their branded product, and to choose which one of them to take.

During that time, what happens in the marketplace is that the formulary or the tier that Galderma's branded product is on drops. Right now it's tier two which means that the co-pay is a certain price. And what happens is insurance companies will say, We're not going to allow an insurance -- the pharmacy to fill the branded drug product. And even if those products are taken off in the marketplace -- and by the way, the only thing that can happen down the road is that Teva's product is removed from the marketplace.

In the event that the Federal Circuit -- if there's no injunction issued, the Federal Circuit reverses, and then this Court issues an injunction, or there's a trial and the Court orders an injunction, but Perrigo's product stays there. Galderma's product never goes back to tier two. It stays at tier three. It stays as a branded drug that is disfavored, and it can never recapture the price that it was going to sell at before.

So we've cited a number of cases in which the Sanofi case which involved Plavix, the Cyclobenzaprine case by Judge Robinson where they talk about these types of harms, market share, price erosion that are cognizable irreparable harms. What makes this case different than all the cases we've cited, all 42 of them that I've looked at is that there's no situation like this where you're going to ensure that another generic comes into the marketplace and which can't be undone. That is the very definition of irreparable harm.

And so for all the reasons we've laid out and that Dr. Hausman explains in his declarations and Mr. Gambino explains with specificity as to what happened at Galderma specifically, including the R & D and the rosacea, that education that Galderma's definitely supported for years because this has been an important part of their dermatological program is this issue with Perrigo and how

it's not addressed by them and can't be remedied down the road.

And so we'd ask that the Court issue an injunction until the pendency of the appeal through the completion of the appeal, and then depending on what happens on the appeal, we'd have to look at what happens next. But if they're right, they're going to launch at the end of this appeal. If they're wrong, then we kept Perrigo off the marketplace, which should have happened because there should have not been a launch by Teva if they're wrong, and Teva's kept off of the marketplace after the few weeks of profits that they've already made.

THE COURT: All right. Thank you, Mr. Alibhai.

MR. ALIBHAI: Thank you, Your Honor.

MR. FLEMING: Good afternoon, Your Honor.

THE COURT: Mr. Fleming.

MR. FLEMING: Yes, sir. Good to see you again, Your Honor.

Thank you. So Your Honor, I want to upfront -- and I am going to focus on just irreparable harm. I'm not going to talk about merits.

THE COURT: I had thought as much.

MR. FLEMING: But I want you to understand that while there may be harm, it's not irreparable harm.

THE COURT: So what about the thing that

Mr. Alibhai is concentrating on which is the scenario that I don't grant the injunction, the Federal Circuit doesn't grant an injunction, Perrigo enters?

MR. FLEMING: Let me explain to you the status quo. I think that's what you're getting to. You're getting at the Perrigo, what's going to happen if you do and if you don't grant the injunction.

THE COURT: Okay.

MR. FLEMING: All right?

THE COURT: If you know the question I'm asking, go ahead and answer it.

MR. FLEMING: I think I do because, first of all, let me tell you, with all due respect to counsel here, they have completely mischaracterized the Perrigo contract. And they were able to do that because they never showed it to you, but I'm going to show it to you.

And what I'm going to show you, Your Honor, is the bullet point from the bottom where is: What is the status quo? The status quo is a creature of a contract that Galderma entered into with Perrigo.

So this is a self-inflicted wound, Your Honor, because in that contract, it has two triggers for Perrigo to come on the market in 180 days -- actually sooner, but I'll show you the contract. Let's go to page -- go to slide 35.

This is the contract for Perrigo. And Perrigo

has two triggers in this contract, Your Honor. The first trigger is an unauthorized generic. That's Teva.

The second trigger is an authorized generic. It's an alternative trigger. The provision that they talk about where you have to file for an injunction, and then you have 90 days, and if it's granted, that doesn't apply to B, the second trigger.

In their contract, what it says is if all of this happens, you go to the next trigger date which has already happened with the authorized generic. They chose to launch the authorized generic. They chose, by virtue of their contract, to give Perrigo the right to come on.

The only thing stopping Perrigo now is our market exclusivity. That market exclusivity doesn't get preserved.

Under the FDA regulations, which we cited to in our brief, it runs uninterrupted. So if you were to perhaps enjoin Teva, 180 days from now that market exclusivity is gone. And if you look under the Perrigo agreement, the only 180-day delay was from an unauthorized generic because they know they already have market exclusivity.

Under B, there's no 180-day contractual delay. So by virtue of Galderma's own conduct in launching their authorized generic, they have triggered Perrigo. So the status quo is, by Galderma's own doing, the Teva generic,

the authorized generic, and the soon-to-enter Perrigo.

So what will happen if you enjoin Teva is you will leave -- maybe the authorized generic comes off, maybe it doesn't because -- and I'll tell you it may not in a second. But Perrigo's coming on in six months. You've seen nothing in these papers from Perrigo saying, oh, yeah, we're going to agree to this interpretation of the contract. Every time they talk about, well, we'll just reinstate this 180 days, there's no citation. Nobody from Perrigo came forward and said it. Nobody from Galderma came forward and put in an affidavit and said that's our interpretation of this contract. That's just what the lawyers are telling you, and that's not evidence, Your Honor.

But the contract is clear that the second trigger by Galderma's own doing has already occurred. And if that's already occurred, the only -- Perrigo's coming on in 180 days. And I guarantee you Perrigo, who's not a party to this case, is not going to say, oh, well, you know, Galderma's a good guy. We filed and accepted a settlement agreement, and we're not going to do it.

THE COURT: So Mr. Fleming, hold on. Hold on a minute.

So Mr. Alibhai, I did see this in the briefing in fine print somewhere.

MR. FLEMING: Hopefully not in a footnote.

THE COURT: Yeah, I can't remember. I just remember fine print.

What do you have to say about this subsection B here? Because I -- well, just why is Mr. Fleming wrong?

MR. ALIBHAI: Because Mr. Fleming is not reading the entire paragraph.

THE COURT: Okay. Well, tell me what --

MR. ALIBHAI: So the first part of the paragraph is there has to be a first applicant that markets a generic product.

THE COURT: Yeah. Yeah. Use the highlighter because it's a lot of words there.

MR. ALIBHAI: Can we go back to the previous page? So and I think that was -- I think he had that part correct.

So the first applicants, so it's provision A, 181 days after the first applicant goes to market. That's what triggered Perrigo's right to go to market, the first thing that happened ever.

THE COURT: The third party is Teva here; right?

MR. ALIBHAI: The third party who is the first applicant, that's right. So Teva --

THE COURT: So the first applicant is Teva?

MR. ALIBHAI: Right.

MR. FLEMING: A is Teva.

THE COURT: Okay. Sorry. Yes.

MR. ALIBHAI: So Teva first markets a generic product. That's happened. That happened first.

Thereafter, a third party, which is the authorized generic, who is authorized by Galderma again marketing a generic product. So first Teva went to market. Then the authorized generic went to market.

The next paragraph, still 5b says --

THE COURT: Wait. Why are you changing?

MR. ALIBHAI: I'm going to -- he doesn't have -- I was using their slide.

THE COURT: And I'm sorry, can you just go back to the slide we were on? So go to letter B there, B, the license of the patent shall be earlier than A, and blah, blah, blah, presumably or B --

MR. ALIBHAI: Well, there's C, D --

THE COURT: Okay.

MR. ALIBHAI: -- or E.

THE COURT: But I take it they're irrelevant to our discussion?

MR. ALIBHAI: They're down the road.

MR. FLEMING: All the patents are expired or invalidated.

THE COURT: Okay. I can barely understand what's relevant, so let's not think about irrelevant.

Okay. So go ahead, Mr. Alibhai.

MR. ALIBHAI: So this section is called the Licensed Patents Effective Date, it's got A through E. This is the actual agreement which is attached as an exhibit to their response as well as to the declaration of Dr. Hausman.

THE COURT: Okay.

MR. ALIBHAI: And the paragraph continues, "In the event that Galderma becomes aware of the actual date under A or B shall give notice."

THE COURT: Right. So here's where a little highlighting would be helpful.

MR. ALIBHAI: Okay. Ms. Chen, can I have you do that instead of me so I don't do this wrong?

So then it says -- this is still paragraph 5b, so we're in the same paragraph, "Perrigo acknowledges and agrees that the license granted under this Section 5" -- so what we just talked about, all of it is Section 5 -- "does not become effective should a sale occur of a Generic Product that has not been authorized or licensed by Galderma unless Galderma did not within ten days seek a TRO."

So the entire license that would have become effective under paragraph 5 based upon Teva's first launch or even the responding authorized generic launch does not become effective if we seek a temporary restraining order, and keep going down, if within -- if we do that within ten

days, the license shall be effective on the earlier of the date the TRO is denied or 90 days after it was filed.

And then if we keep going down, it says, If a TRO prohibited any further sale of such unauthorized generic product is entered, which is what will happen if the Court enters an injunction, a TRO will be entered prohibiting any further sale of such unlicensed generic product. The licenses shall not become effective until the occurrence of the next applicable licensed patent's effective date.

So the Court will enter an injunction today, and thereafter, sometime in the future, either one of those things in five has to happen again.

THE COURT: So maybe I missed it while you were doing all of this, but in the earlier thing where there was an A and a B, this relates to both A and B?

MR. ALIBHAI: This relates to an unlicensed product which is A, but it relates to all of the licenses. The first sentence says, "Perrigo acknowledges and agrees that a license granted under this Section 5," and this is all Section 5.

MR. FLEMING: Keep reading, should there occur --

THE COURT: Well, so Mr. Fleming --

MR. FLEMING: Sorry, Your Honor. I was just helping.

MR. ALIBHAI: It's not helpful. Does not become effective until all these things, and it says it resets. And that's the way the agreement is drafted, that there's a complete reset if there's an injunction.

Now, Mr. Midgley is here if Your Honor wants to hear from Galderma to say, yes, we agree with this interpretation, but this is an issue of contract interpretation. So I'm not suggesting --

THE COURT: From Perrigo, you mean?

MR. ALIBHAI: No, Mr. Midgley from Galderma is here. He said, Well, nobody from Galderma submitted an affidavit on this. To me, this is an issue of contract interpretation, so it's for Your Honor to decide.

So --

THE COURT: Hold on just a minute.

MS. BEN-AMI: Your Honor, would you like a hard copy?

THE COURT: Sure.

MR. FLEMING: Do you need me to say something so I can explain my position?

THE COURT: No, that's okay. Let me try to figure out Mr. Alibhai first. Which page is this?

MR. FLEMING: Page --

MR. ALIBHAI: Pages 6 and 7 is Section 5b.

THE COURT: So basically the dispute here is

that the position of Galderma is that this large paragraph, the stuff that's up on the screen that's on Page 7 which seems to be referring to a third-party launch is something that basically -- the things that are described in this paragraph happened because of the third-party launch. All the other things that are in paragraph B become inoperative.

Whereas I take it the defendant's position is this only relates to what happens if paragraph A is the reason for the licensed patent's effective date.

That's the two positions; right?

MR. FLEMING: That is correct.

MR. ALIBHAI: Correct.

MR. FLEMING: Because there's the expressed carve-out in that because it says the rights under B should there be an unauthorized generic. That's the A situation. It says nothing about the authorized generic, and we talked about the unauthorized.

But the authorized generic is a separate trigger. So you can have a situation, Your Honor, where there is no authorized generic, which this contract contemplates, and it's only at Teva, unauthorized generic that's out there. And if that happens, then they come in, and they sue, and they try to stop it, and that makes sense.

However, B is a separate trigger which is the authorized generic gives Perrigo rights, too. So even if

you follow what's in the sentence, you see it says the next applicable licensed patent effective date which is triggered by B, the authorized generic which Galderma initiated on its own conduct.

So these are two separate triggers, and this whole 90 days and the injunction, this whole provision is only a carve-out of the rights should there be an unauthorized generic.

THE COURT: So I think I understand what you just said there, Mr. Fleming, essentially which is essentially that this paragraph, the big paragraph we're talking about applies to A, and Galderma's presumably doing what's required by that. But then the launch two days later, whatever it is that the authorized generic is, then the next applicable licensed patent's effective date?

MR. FLEMING: That's exactly it, Your Honor. And by virtue of that, now there's an authorized generic. And in six months, by April of 2020, there's going to be Perrigo on the market as well. They're coming on.

THE COURT: I can't say that I'm going to be able to resolve this sitting here right now, but at least I understand, Mr. Fleming, your position.

And Mr. Alibhai, I understand yours, but you can certainly talk more about it.

MR. ALIBHAI: Let me tell you more why it's not

the way that they are reading it because they keep saying this 5a thing; right?

THE COURT: Yes.

MR. ALIBHAI: The first sentence of the second paragraph 5b, the first full paragraph on Page 7, it says, "Perrigo acknowledges and agrees that the license granted under this Section 5" -- it doesn't limit it to A. It says this Section 5. This is all Section 5 we're talking about.

And then go down to the last two lines of that paragraph, the licenses plural. So whatever happened before, plural. The licenses shall not become effective until the occurrence of the next applicable licensed patent's effective date.

So we reset after the injunction. There are no licenses. That's what it expressly says.

And by the way, Your Honor, if Perrigo tries to launch, Galderma will seek an injunction against it because it will not have been licensed under this agreement. If this Court issues an injunction, Galderma has expressed that it will seek an injunction against Perrigo because no licensed patent effective date has occurred.

THE COURT: Okay. Well, I'm not sure what your point is about the licenses on the next-to-the-last line of this being plural.

MR. ALIBHAI: Because they're trying to say it's

an A thing, not a B thing. They're trying to parse this out. The way this entire paragraph is written is that the license granted under the Section 5, it's talking about the entire Section 5, and it's talking about all the licenses shall not become effective. So whatever happened before doesn't happen until the occurrence of the next applicable licensed patent's effective date.

THE COURT: So let me ask you this: So if Teva had not launched, but instead you authorized Prasco to do the authorized generic, then this whole big paragraph would be completely irrelevant, and Perrigo could just, pursuant to the subsection B, launch?

MR. ALIBHAI: No, because Perrigo could never launch until Teva's 180-day exclusivity was -- the other only thing that was causing --

THE COURT: So they could wait 180 days even though Teva can't do anything? Oh --

MR. ALIBHAI: 180 days after Teva launches. So the statutory protection that Teva has, even if a license -- even if the license becomes effective as to Perrigo, it's still precluded from going to market until Teva goes to market first, unless Teva has forfeited, waived, or relinquished its exclusivity.

So yes, even an authorized generic would not have put Perrigo on the market. The only thing that put

Perrigo on the market was Teva's launch.

THE COURT: And so actually, there must be an obvious answer to this, why doesn't Teva's exclusivity keep you from doing the authorized generic? Is that just a different provision of the statute?

MR. FLEMING: Yes, it doesn't apply.

MR. ALIBHAI: It doesn't apply.

THE COURT: I said there might be an obvious answer.

MR. FLEMING: Well, Your Honor, the generic is essentially a loophole in the law actually, and I would like to talk -- I'll talk to you for a few minutes about what that means for them.

THE COURT: All right. So Mr. Alibhai, I should give Mr. Fleming a little bit more time. Okay?

MR. ALIBHAI: Sure.

MR. FLEMING: And Your Honor, you put your finger right on it, Your Honor, because what it says there is they agree that the grant under Section 5 does not become effective should it occur of a generic product that has not been authorized. So the only carve-out of that big paragraph is for an unauthorized generic.

Let's assume Teva wins, but they waive their 180 days, and they launch an authorized generic. That means under their provision, Perrigo comes into the market right

away, and they can't stop them. That's their contract. They've done it. They may want to rewrite this, Your Honor, but that's the contract they have.

And by virtue of them launching the authorized generic, they have implicated the trigger. And by implicating the trigger, they gave Perrigo the rights, and those rights run. And to change the marketplace now will only harm Teva.

Why? Because 180 days, as you saw in the briefing, the FDA regulations, runs from the time it was the launch of Teva, and it runs uninterrupted. And Your Honor, I suspect that it's going to take more than six months for whatever is going to happen in the Federal Circuit to happen, and that would mean that the valuable -- the most valuable assets sometimes for generic launch is that exclusivity, as you know.

THE COURT: Yeah, I have heard that before.

MR. FLEMING: And that will be lost. So that is what is really here. And the reality is the status quo is that there's three generics in the marketplace, and it's due to Galderma. As much as they want to push it on Teva, it's Galderma's own doing because that's the contract they signed. Maybe they don't like it. Maybe they think -- they probably shouldn't have launched the AG and then they wouldn't have that long paragraph. But they launched, and

they took it.

But what does it mean for them to launch? Can we go back to 31 for a second? Thirty-one, please. Okay.

And let's look at the last line. So let me explain a little bit about the situation with Prasco. Maybe Your Honor may not be entirely familiar, so what happens is when Galderma authorizes Prasco to distribute what is essentially Soolantra, they enter into a contract. And under that contract with Prasco by industry standards, Galderma receives 90 percent of the profits that Prasco receives from selling.

THE COURT: And your point is?

MR. FLEMING: My point is that they're receiving a tremendous amount of value through the sales of the AG. They're not out there losing.

THE COURT: Yeah, but I assume from the branded thing that you're receiving 98 percent of the profits.

MR. FLEMING: That's not necessarily true, Your Honor, because if you remember -- could I have slide 32?

So if you remember, Mr. Hofmann did an analysis. Remember the CareConnect and the discounts and rebates that Galderma had to give to get to the zero co-pay? They were giving up already more than 52 percent of the WAC price to get down there.

But what's really important to consider, Your

Honor, is people like Dr. Gallo who couldn't prescribe Soolantra when it was a branded product because the VA wouldn't pay now can actually prescribe it because it's an authorized generic. And so what they probably did by issuing the authorized generic is expand their marketplace to all of those entities that couldn't otherwise do it.

But Your Honor, let's go back to 31. These harms, should they even occur because there's no evidence that anything has occurred, should they even occur are all remedial by money: lost sales, price erosion, market share erosion. These are the quintessential patent damages, parade of horribles that are quantifiable and have been quantified in your Court, I'm sure, time and time again.

THE COURT: Usually a lot of argument from the defendant.

MR. FLEMING: But it's only as to quantum, Your Honor. They only argue as to quantum.

THE COURT: No, there's lots of arguments that, no matter what methodology, the plaintiff does not comply with any known economic standard.

MR. FLEMING: Yeah.

THE COURT: You probably made those arguments a few times yourself.

MR. FLEMING: I wouldn't be surprised, Your Honor, but it's become a hot bed of dispute. But one thing

to understand, this parade of horribles about the lost revenues, this product is but three percent of Galderma's --

THE COURT: But I do think, you know, they're not saying that you're driving them out of business, so I don't see what the fact is whether they're a big company like they are or even bigger company, as I think you are, what difference does it make?

MR. FLEMING: Well, first of all, what it makes a difference on is when they say, well, we're not going to have any money for our R&D, and we're not going to have any money for research and development, well, that's just not true, not from the looks of this.

THE COURT: No. No. I --

MR. FLEMING: That's what I'm addressing there.

THE COURT: Okay. Yeah. Yeah.

MR. FLEMING: That's what I'm addressing.

THE COURT: Yeah. You know, every time you take a dollar away from somebody, you have to decide how they're not going to spend that dollar.

MR. FLEMING: Right. And so fundamentally, fundamentally, when the customers that are lost -- and as they say themselves, these market players, whether it's metronidazole or Finacea, that's all -- they're already out there competing. You know, they already know who gets what shares of market and who gets what customers.

So should there be this proof that Teva's product is taking customers away, they know where it's going to come, and they know how to count them. They know how many units, you know, how much profit. That's all quantifiable money, damages, quintessential stuff.

Those are not irreparable, Your Honor. And while I never want to talk about anybody losing their jobs, I hate even the concept of that, in this industry, people get put on, people get taken off, people get reallocated. It's not their only product in this branded area. It's not the only product that they're selling. And that's something that can be readjusted should there come a time where they're ultimately taking everybody else off the market.

But more importantly, what's really the key here for you, Your Honor, is that they have created a situation where there will be a genericized ivermectin market because of their own contacts -- because of their own conduct and because of their own contract. That is the status quo.

And everything else that follows through this, the lost sales or the lost price erosion, that's all going to be quantifiable and remedial. That's all going to be there.

What's not remedial, what's not curable, what's not fixable is the loss of market exclusivity and the value that that has to a generic who's undertaking the effort to

come to a Court like yourself and ask for your ruling and take the patents that were in the Orange Book.

THE COURT: I think they were the ones who -- no actually, I guess, in this case, you guys were the ones who came here. Yeah, that's right. Okay. I remember that.

MR. FLEMING: Thank you. Your Honor.

THE COURT: All right. Anything else, Mr. Alibhai, that you want to say?

MR. ALIBHAI: Just a couple quick points, Your Honor. The argument that was just made to you about erosion of markets, customers, and prices, the Abbott case we cited, the Purdue case we cited, and the Sanofi Cipla Lab case we cited say that that is rarely reversible. And the thing that they fail to address, and he said it again is, oh, well, there will be a Teva, and they'll just be able to figure out what Teva got.

It is undisputed that if the Court does not enter an injunction that Perrigo will go to market in 165 days, and there's no way to stop that. But the entry of the injunction under 5b under Galderma's interpretation and Galderma's enforcement of that provision will ensure that Perrigo does not go to market and that it goes back to the way it was until the Federal Circuit can look at these issues.

This is a major part of Galderma's

pharmaceutical business. It accounts for 31 percent of Galderma's pharmaceutical business. It has three products. It's a big company, and it does a lot of other things.

THE COURT: Yeah, but I was going to say, yeah, because I saw the figure of $90 million for the net revenues of this and 900 million for the net revenues of Galderma.

MR. ALIBHAI: I don't think it's fair to look at -- a couple of things. I don't think it's fair to look at worldwide business of Galderma which includes selling Cetaphil such as a soap or which includes selling injectables. But if we're looking at the prescription drug --

THE COURT: But you are one company, so you know, breaking it down into little pieces and saying, well, this little piece is a big part of, you know --

MR. ALIBHAI: Well --

THE COURT: -- I'm not too sympathetic to that.

MR. ALIBHAI: Well, what I think the Court should be sympathetic to is looking at Soolantra by itself. The Soolantra market will be decimated as it comes to Galderma, and there will be actual layoffs. There will be people losing their jobs. There will be an effect on this business segment. That's not really disputed.

And because of that harm, actual tangible harm, they just keep saying that we'll be able to quantify it down

the road. I don't think they'll say that a year from now. You'll hear the exact opposite.

THE COURT: No. No.

MR. ALIBHAI: And that's why --

THE COURT: So I have a case that I got from Judge Robinson where she had granted preliminary injunction which the Federal Circuit later vacated and said plaintiff had no case, and the plaintiff had to put up millions and millions of dollars as a bond. So I've seen all these issues before from in reverse because I had to figure out, because if it turns out, having done this, when you put up a bond and then it turns out you prevented the defendant from entering in the market, they have damages, and so you have to figure this stuff out. And I found out that you don't have a jury do this. The judge has to do this.

MR. ALIBHAI: That's correct.

THE COURT: So the concepts, a lot of these concepts, I've seen them before. You know, in the end, we were able to issue an opinion saying what we thought the damages in that particular case was.

You know, and maybe one of the things that's kind of different here now is it's different when you're looking back at what happened, and you're trying to figure out, okay, what's supposed to make it right.

Here, you know, there's a lot of predictions.

And so to get to your point, you know, Mr. Fleming, will be arguing the opposite in two years, one of the most frustrating things about the case that I had a year ago to do this was the parties' positions were diametrically opposed to what they had been at the preliminary injunction stage where the plaintiff said, you know, it will be the end of the world if the preliminary injunction is not granted.

And by the time when we were trying to decide how much damage they had done, they said, nothing happened. We did it in a hurry. We didn't have a chance to think about this, and we were all wrong. And now we've spent more time and nothing happened. And of course, the defendants were also, likewise, reversed.

So I expect that if it suits everybody, you can take diametrically-opposed positions sometime in the future. That's just what we all --

MR. FLEMING: Hopefully, I was more persuasive today.

MR. ALIBHAI: Well, Your Honor, what I'm looking at is a body of law that we've cited, both from the Federal Circuit and from courts in this district. Right. Opinions from Judge Sleet and Judge Robinson that address this issue and this type of situation, and say, Look, the Federal Circuit has often said -- and you know, there was a quote from Judge Robinson in Cyclobenzaprine. She said, "In every

ANDA case, there's a likelihood of irreparable harm for the brand because a generic has already made markets flood." That's already happened.

And the price of Soolantra is dropping. This is not Galderma's doing. This is Teva's doing. Teva chose, knowing that we did not want to have a generic in the marketplace, that we were opposed, and that they we would seek injunctive relief, if necessary, to go ahead and launch without notice.

THE COURT: So Mr. Alibhai, I'll tell you what, why don't you let me just take a little recess here, and I'll come back in a little while and tell you whether or not I'm going to issue any ruling today.

Okay?

MR. ALIBHAI: Yes, sir.

THE CLERK: All rise.

THE COURT: So we'll be in recess.

(Recess was taken.)

THE CLERK: All rise.

THE COURT: All right. Be seated.

So let me try to address the issue that we're here to address, and I do believe that the applicable rule here is Rule 62(d) which says and I quote, "While an appeal is pending from a final judgment that refuses an injunction, the Court may grant an injunction on terms for bond or other

terms that secure the opposing party's rights."

And I left out a lot of the intermediate words that aren't particularly pertinent here, but obviously, in the ANDA case when I find a patent invalid, I'm refusing to grant an injunction against the defendant, so that's why that applies.

And I have cases, and I'm quoting from one of Judge Stark's cases from earlier this year which relies on the U.S. Supreme Court which is pretty good authority for what the standard is on to succeed on a motion for an injunction pending appeal.

And I'm quoting here, "Plaintiff needs to show a strong showing that it is likely to succeed on the merits in this appeal, that absent an injunction will be irreparably harmed, and that an injunction or stay will not substantially injure the opposing party, and an injunction will not harm the interests of the public." And that's from Cipla Limited versus Amgen, 2019 Westlaw 2053055, District of Delaware, May 5 of 2019.

So on the question of the merits and the likelihood of success on appeal, whether or not a substantial issue is raised, I think plaintiffs have raised a substantial issue with the opinion, and I think Mr. Wilson fairly straightforwardly in his argument expressed what that is. I thought that the defense of my opinion by Teva was

not very strong which gives me some sense that the arguments they're going to make on appeal are going to be different than what I said, so I'm not real confident that I'm going to get affirmed on this. And I say that against the backdrop that it does strike me, though I haven't thought about it and I can't really think about it now, that it may be at the end of the day that even though the patents are not anticipated, they're obvious.

I mean, I do think the case -- I think it's Perricone, in my opinion, is a bad case for plaintiff. And you know, I think taking a disclosed method and a disclosed compound, and then claiming the method, the known method of administering the compound and then saying, Well, here's the results we got in the clinical trials, we'll add them in, and now we've got a new patent, that strikes me as if plaintiff can really do that, that's not very good for the system. But based on what I've written so far, I do think plaintiff has a good argument or a decent argument that maybe I got it wrong.

On the question of irreparable harm, much of what I read in the briefs, or in the -- briefs is probably the right word, but in the declarations of the economist, it made me think that, generally speaking, a lot of damages or harms, financial harms in this case, they could be measured down the road, and they could be measured in similar fashion

to how they're generally measured in other patent cases.

But I also thought, which maybe it was in the briefing, but I hadn't fully appreciated in the briefing, it does seem, based on what I saw of the contract, that there's at least a reasonable argument that if I grant the injunction, Perrigo won't be able to enter the market until after Teva, or until 2024, or thereabouts. But that if I deny the injunction, assuming the Federal Circuit doesn't reverse that decision, they're going to be on the market stay.

And if it turns out that I'm wrong on the anticipation and it gets reversed, that seems to me to be a harm that the loss that's created by Perrigo as a result of what Teva has done is not something that anybody will pay for. Perrigo is certainly not going to be liable, but I don't think Teva would be liable for the harm Perrigo causes, and yet that would be a real harm that flows directly from not granting the injunction. So I think, though I was initially dubious about there being irreparable harm here, I think actually there's a decent likelihood there would be irreparable harm.

On the other things, I'm unclear, as I sit here right now, as to how much harm there will be to Teva. I'm going to impose a bond so just the delay in launching, that harm will be covered. I'm unclear on whether or not the

180-day exclusivity will be forfeited or not. If it is, that is a substantial harm to Teva. And for purposes of this, I'll assume that that's the case.

In terms of how the injunction would affect the interests of the public, you know, that seems to be kind of balanced because, on the one hand, plaintiff has its patent rights. You know, there's a lot of investment in new drugs, so I don't think this is particularly a new drug investment.

You know, on the other hand, the public's going to not get the benefit of the generic pricing which is a large part of why we have these cases. And so I think there's something on both sides there. But on balance, weighing all those things together and exercising my discretion, and I certainly don't like to exercise my discretion this way, but I am going to grant the injunction pending appeal, and basically there is a question of what the bond should be.

Is that something that either of you care to say anything to me about? Start with you, Ms. Ben-Ami or Mr. Fleming.

MS. BEN-AMI: Well, I'll give it a shot, Your Honor. I think, first of all, we'd like to make a motion to stay your ruling pending the appeal of your ruling.

THE COURT: No, you can -- well, actually I will stay it for three days. Or wait, what is today? Today's

Thursday. I'll stay it until Tuesday of next week, and then you can go to the Federal Circuit and see if they want to stay it.

Okay?

MS. BEN-AMI: Okay. I know you don't want to hear my bases, so since you granted it, I won't waste your time.

I think that the FDA has stated that the 180-day exclusivity period runs from the first day that there's a launch, and that is gone based on your ruling. That's gone.

THE COURT: All right.

MS. BEN-AMI: And the implications of that are Perrigo comes on the market because you didn't see Perrigo coming in here and saying, oh, yeah, we agree. You didn't see a declaration.

THE COURT: Okay. Yeah. Okay. Let's just get to the point here.

The bond, how much?

MS. BEN-AMI: Right. The bond should go for the amount through 2023, and we'll have to come up with that amount because there will be a loss assuming if we're right.

THE COURT: And so you must have at least thought about this number.

MS. BEN-AMI: No.

THE COURT: No. Mr. Fleming, have you thought

about it?

MR. FLEMING: No, Your Honor.

THE COURT: Okay.

MR. FLEMING: We're trying to. I'm trying to talk to the client while we're here, but --

THE COURT: All right. Have you all thought about it, Mr. Alibhai?

MR. ALIBHAI: I did, Your Honor. So as I said to Your Honor, it's my view that the issuance of the injunction will mean that the clock will reset. Perrigo will not come in the market.

THE COURT: Right. But let's assume, because I just said I'm going to assume that they will actually lose their exclusivity, so factor that in.

MR. ALIBHAI: If I were to factor in that they're going to lose their exclusivity, which obviously we disagree about that, then it should be looking at what they would have made in a market in which there was Galderma, and an authorized generic, and them --

THE COURT: All right.

MR. ALIBHAI: -- for six months.

THE COURT: So tell me what you think that is.

MR. ALIBHAI: So we know that the marketplace is approximately today around $90 million.

THE COURT: So, but you know, I don't think

that -- the six months is not right because the appellate process is going to play out probably over 14 to 16 months, and they are going to be off the market, assuming that I don't get reversed on this, for that entire time; right?

MR. ALIBHAI: They would be off the market if you're not reversed during the time that the appeal is pending.

THE COURT: Yeah.

MR. ALIBHAI: We could expedite the appeal.

THE COURT: Well, you know, as the Federal Circuit likes to say, you can self expedite. I don't know that they'll -- and in fact, so far you have done the opposite of self expediting.

MR. ALIBHAI: I wasn't aware they were going to launch, but I understand, and I'm willing to expedite. But you would look at this marketplace which is a 90-million-dollar revenue -- we're not talking -- and then you'd have to take a segment of time of that, and then you'd have to divide up how that marketplace would look as to what Teva was making, what the authorized generic was making, and what Galderma is making, because it's a portion of that.

THE COURT: Well, do you agree that, generally speaking, what Teva loses by not launching is some fraction of that $90 million because they're probably not going to be getting back all that many people to switch from some other

treatment to generic Soolantra. They're going to be getting branded Soolantra, for the most part, to move to generic Soolantra; right?

MR. ALIBHAI: Well, during this time period, there's going to be some amount of product that they've put in the marketplace and that they can continue to put in the marketplace until Tuesday. And what the evidence shows is that can be up to six months' worth. And so they have to tell us how many units they've put out there because they're going to make money during this next few months from its continued sale. So they're still getting some benefit for months to go.

So it's a fraction of the revenues, and then we'd have to look at profits on that because they don't get net revenues, they get profits on it. Right. Just regular patent infringement damages are profits not revenues.

THE COURT: Right. So give me a number.

MR. ALIBHAI: Well, my number based on the time value of money because I think they're going to make this money in the future, but I think the number is in the low single-digit millions based upon a $90 million market, and then three players in the market place, if that's what would be happening today, and then dividing that up. And you have Mr. Bart's declaration at paragraph 13 where he said people were buying the authorized generic, not theirs.

THE COURT: Yeah. Yeah. I mean, I think he said one person. He didn't say -- that wasn't a study or anything.

MR. ALIBHAI: I don't know what he said in terms of how many people it was, he just said that generally. But again, it would be the profits that they're losing in today's marketplace as it exists which I think is a low millions number because they only hope to make 20 or $30 million in revenue at best from the numbers that I've seen.

THE COURT: All right. Mr. Fleming, do you have something to add?

MR. FLEMING: Thank you, Your Honor. We have done some discussion. I've done a quick calculation in my head based on the numbers. You're right, this is going to be an 18-month process in a 90-million-plus-dollar market. We would ask for a bond of $75 million.

THE COURT: Billion?

MR. FLEMING: Million. I'm sorry, did I sound like that? I didn't mean to go like that. I meant million.

THE COURT: Well, I don't know. That's what I heard, but I think you're wrong. Well, that seems a bit excessive --

MR. FLEMING: Well, Your Honor --

THE COURT: -- but go ahead.

MR. FLEMING: May I? Thank you.

So what I want you to understand is the 180 days is going to be gone in six months, and that was a criterion by which the decision to launch hinged. So in the absence of that, we run the real probability that the economics of this to a generic because, Your Honor, I will make a side wager with you about what happens with Perrigo in six months. But what I will tell you is because of the value that that exclusivity gives to a first entrant, you know what a first-market entrant does, to be a second and perhaps now a third-market entrant with the AG, that is destroying in value to Teva. So that number is nowhere near as exorbitant as it may sound on the merits given that.

THE COURT: Well, so let me ask this, and I'll give you a few more minutes to confer, if you want, but what was Teva estimating its profits would be from the first year? I mean, I'm sure they study this thing, and they have a total estimate.

What were they projecting?

MR. FLEMING: Your Honor, I think roughly $25 million.

THE COURT: Okay. All right.

MR. FLEMING: And that's net. That's net.

THE COURT: Yeah. Yeah. But I mean, presumably that's what we're talking about here.

MR. FLEMING: I would think so. I would think so. So now you've got an 18-month period, and you've got the loss of the market exclusivity as a multiplier. You have to take that into account.

THE COURT: All right.

MR. FLEMING: It's at least a two times multiplier. And Your Honor, what I would ask you to do is order them immediately to stop sales of the AG.

THE COURT: Well, what do you think about that?

MR. FLEMING: They said they were going to do that if you enjoined us, so let's hold them to what their word is.

MR. ALIBHAI: If the Court issues an injunction, prohibits Teva from further sale and recalling the generic that's in the marketplace --

THE COURT: What if I don't recall the generic?

MR. ALIBHAI: If you don't recall the generic?

THE COURT: Because you were certainly talking a minute ago like I wasn't going to.

MR. ALIBHAI: Well, I think you should because, otherwise, they're asking you for a bond while they continue to make profits. That $25 million number you just heard assumes six months exclusivity.

So putting a multiplier on a number that's already got the six months exclusivity, it makes no sense.

So the purpose of the bond is to create some protection. If we need to have hundreds on this, then we think the Court should issue a small bond, so the thing can go -- so the injunction can go into effect. We can submit briefing and evidence because they have numbers they've created, and we've never seen those, and so we'd be able to look at that and make a proper determination.

THE COURT: So my recollection from having done this before is the bond, as I said, acts as sort of a cap as to what the damages down the road can be. So there's --

MR. ALIBHAI: That's correct.

THE COURT: -- not much incentive to -- so from my point of view, the incentive is to risk -- give them too high a bond, not too low a bond.

MR. ALIBHAI: I'm saying that we need to have further discussion about this because they've not produced documents or shown us how these sales forecasts work. You have a $90 million market that they would not have gotten all of. You take the profits of that, and you have to take into consideration that their price is lower than what Galderma was selling at.

They haven't told us what price they're selling at. I don't know what price they're selling at, so you have to factor in all these issues. The amount of profit that they would have made is nowhere near $25 million, in my

opinion, in the first year. It's impossible to say a 90-million revenue would have turned into 25 million of profit for Teva with price erosion with an authorized generic.

But to answer the question that you asked me, we will instruct the authorized generic not to or to stop the authorized generic.

THE COURT: Mr. Fleming, what do you have to say about recalling the six months of product that you had out there?

MR. FLEMING: Well, Your Honor, I think that's a gross overstatement. My information was it's more like two months.

THE COURT: So what about recalling the two months?

MR. FLEMING: Well, Your Honor, the problem with that is we have contracts now for distribution and sale of this product, so we're going to have to go to our customers and pull the product back. It's just grossly unfair to do that. We should be able to at least sell off the product we have based on the contracts that we've made with these clients in good faith. They bought it from us in good faith, and we should be able to deliver on those contracts.

Excuse me. I will tell you that the $25 million number that I gave you was a forecast based on all of these

variables. Galderma is a big company. They know how these numbers are calculated. To profess ignorance of it is almost an insult to the Court. We know, and I'll tell you that that $25 million number was a 12-month projection.

THE COURT: I don't take it to as an insult to the Court. They don't say how generally one does this kind of thing. They said they don't know how specifically you did it, and they don't. Right?

MR. FLEMING: It's the information that these companies is out there, but, yes, they know what their generic is selling at. They priced it against our products, Your Honor. They know how -- any way, Your Honor, what I would say to you is let me answer your question, let us sell out based on our contracts. Let us meet our contracts that are currently in place.

And also, I will tell you that the number that I gave you took into account the variables that Mr. Alibhai said that he didn't understand. I hope I answered your question.

THE COURT: Maybe.

MR. FLEMING: I'll stop because often times I speak so much, you forget what your question was.

THE COURT: Okay. Mr. Alibhai.

MR. ALIBHAI: Well, that goes to the amount of the bond, too. If they're going to sell for two more

months, and if Your Honor is going to stay the injunction until Tuesday, that doesn't stop them from entering into new contracts and then fulfilling them.

THE COURT: Okay. Well, there are no new contracts. You know, the only thing that I'm staying until Tuesday or the only thing -- let me think about this real quick.

So actually on balance, it occurs to me that I don't know that much about this industry because after all, Mr. Fleming, when you say you have contracts, there are contracts where you've already delivered the good, and there's contracts that provide you to be -- because I think I saw in the briefing Walmart, and maybe that was the authorized generic. I can't remember, but I saw --

MR. FLEMING: We have agreements with, contracts, purchase orders, however you want to describe it where we have made commitments to clients, to customers to deliver product to them.

MR. ALIBHAI: And our belief, Your Honor, is they should not be able to make those deliveries.

THE COURT: Okay. So based on what I've said about, among other things, irreparable harm, and also to some extent what I think are or what seem to me as likely to be -- maintaining the status quo, I don't think Teva should ship any more product. I'm not going to make you recall

product that you've already put on a truck to somewhere else. And it just seems to me based on what I've said, and I guess maybe to the extent that Ms. Ben-Ami earlier said can it be stayed until next Tuesday or some short period of time, you know, maybe I thought about that too quickly.

So based on everything that I've heard and taking into account that I think that Teva's six-month exclusivity may be lost, I'm going to enter an injunction orally today, in writing tomorrow, no more shipment by Teva. No recall of the product by Teva. The authorized generic is cancelled.

And in fact, do you know -- so I take it you shipped some authorized generic, too?

MR. ALIBHAI: That's correct.

THE COURT: And do you want it out there, or do you want to recall it?

MR. ALIBHAI: If you're going to leave the other product out there, we believe you should leave that product out there as well.

THE COURT: All right. How much have you shipped?

MR. ALIBHAI: I think it's a few weeks of supply.

THE COURT: All right. And you're representing you've shipped two months of supply?

MR. FLEMING: I've heard that number, Your Honor, but I know I've been told it's not six months. But whatever -- right, whatever is out of Teva is out of Teva.

THE COURT: All right. Whatever is out of plaintiff is out of plaintiff, but nobody is shipping any more product. And my inclination is to require Galderma to post a bond of $40 million which is based on the representations about what Teva's expected profits are and based on the possibility that I think is real that they're going to lose their exclusivity.

And I want to make sure that there is enough money to cover the harm to Teva that if it turns out that the silver tongue warriors for the plaintiff have caused me to do something I shouldn't be doing here.

Is there anything else we need to address today?

MR. FLEMING: No, Your Honor.

MR. ALIBHAI: No, Your Honor.

MR. WILSON: Would Your Honor like us to submit a proposed order or you're going to draft one?

THE COURT: Well, there was with the motion of proposed order. I would certainly not be adverse to your modifying it and talking to each other before you modify it to incorporate what I've said here today, and then hopefully submitting it jointly. But if you disagree, then submitting it also with a Word version that we can edit.

MR. WILSON: And I did have one question which is the three-day stay, you decided against?

THE COURT: I've decided against that.

MR. WILSON: Okay.

THE COURT: Okay. And I'm sorry to do this, do you think you can talk to each other and submit hopefully a joint proposal tomorrow at some point or at least submit competing proposals? I mean, I didn't look at it real closely because I didn't really think I was going to be granting this. You know, I saw that there was a three-page submission.

MS. BEN-AMI: Can we have until Monday?

THE COURT: Well, as long as you're not shipping any product until Monday.

MS. BEN-AMI: I think you've enjoined it.

MR. ALIBHAI: If the oral order is by Monday binding, and they accept that it's binding.

THE COURT: Well, Ms. Ben-Ami just indicated she did.

MR. ALIBHAI: So then we're not opposed to that.

THE COURT: And then we've got representatives of both Teva and Galderma here, and I assume the representatives are basically lawyers, too. So no more shipping of product, $40 million bond, but no recall. And let's get some language for injunction, and then you can go

visit the Federal Circuit and see how many different times you can get me reversed.

Okay? Thank you.

MR. ALIBHAI: Thank you, Your Honor.

THE CLERK: All rise.

(Court was recessed at 6:02 p.m.)

I hereby certify the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Heather M. Triozzi
Official Merit Reporter
U.S. District Court